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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,698

11/05/2003

Ricardo Blank

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1095

7590

06/06/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/701,698	Applicant(s) BLANK ET AL.	
	Examiner MICHAEL G. BOGART	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,7,8 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,7,8,10-24 and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 April 2008 has been entered.

Claim Objections

Claims 28 and 35 are objected to because of the following informalities:

2. Claim 28 recites the limitation "the adhesive layer" in line 4. There is insufficient antecedent basis for this limitation in the claim.
3. Claim 35 includes the limitation "device sealing engaging the inner surface" which is awkwardly phrased.

Appropriate correction is required.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 2, 3, 8, 10-18, 20-24 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2 and 20 combine the threaded frame attachment assembly of the embodiment of figures 1-3 with the means for connecting the connector to both the exterior and the interior surfaces of a laminated paper packaging system of figure 5. There is no disclosure or suggestion in the specification or claims to combine these two different means of attaching the connector to the paper packaging system.

Claims 3, 10-18, 21-24 and 29 are rejecting as being dependent upon claims which do not comply with the written description requirement.

Claims 27 and 28 combine the exterior surface adhesive attachment assembly of the embodiment of figure 4 with the means for connecting the connector to both the exterior and the interior surfaces of a laminated paper packaging system of figure 5. There is no disclosure or suggestion in the specification or claims to combine these two different means of attaching the connector to the paper packaging system.

Claims 8 is rejecting as being dependent upon claims which do not comply with the written description requirement.

Claim Rejections – 35 USC § 103

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The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

5. Claims 7, 19, 30-34 and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi *et al.* (CA 2 432 623 A1 or US 2004/0104246 A1; hereinafter “Kawaguchi” all page numbers, reference numbers and figures below refer to the Canadian patent) in view of Tallman (US 4,881,662).

Regarding claims 7 and 30, Kawaguchi teaches a connector device (12) capable of connecting a feeding line (30) of an enteral administration set (30, 31) to a laminated paper packaging system (20) containing a composition, the connector device comprising:

a rigid tube part (112) capable of being sealingly attached to the feeding line (30) of the enteral administration set, the tube part (112) defining a first part of the a passageway (112g, 112c) allowing the flow of the composition contained in the laminated paper packaging system (20) to the feeding line (30) of the enteral administration set (30, 31), and

a tubular first spike (112a) capable of penetrating a first surface (20, 21) of the laminated paper packaging system (20) and defining a second part of the passageway (112g, 112a) and attachment means (112b, 114) for attaching the connector device (112) to the exterior surface of a paper packaging system (20)(see figs. 1 & 6, *infra*).

FIG. 1

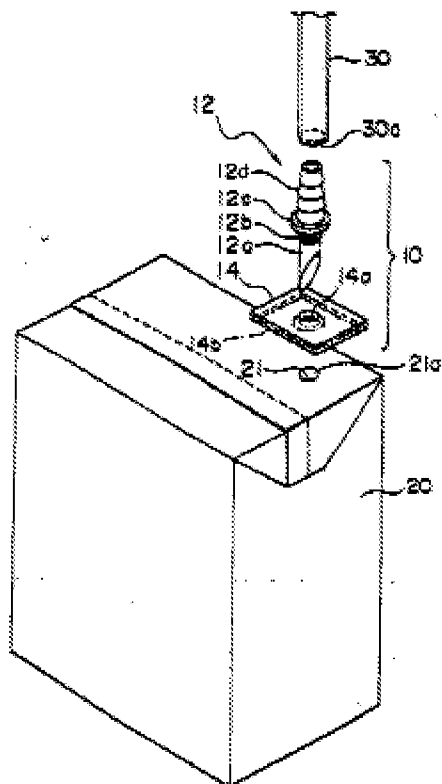
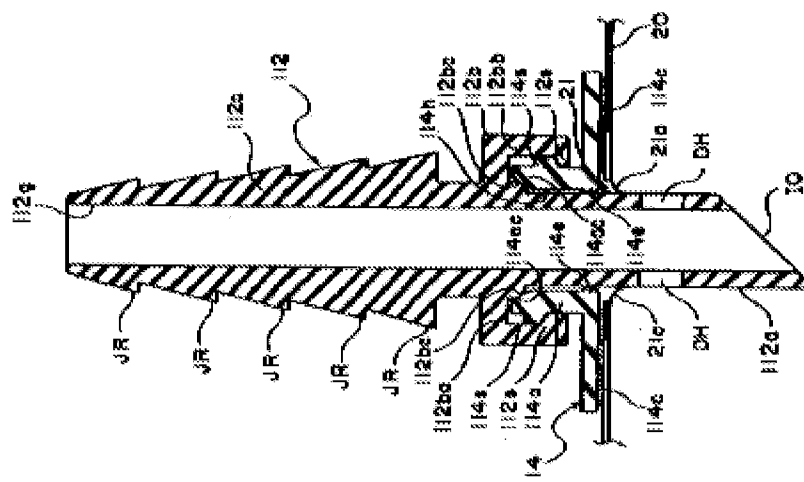


FIG. 6



Kawaguchi does not teach an attachment means fixedly attaching the connector device (12) to an interior surface within the paper packaging system (20).

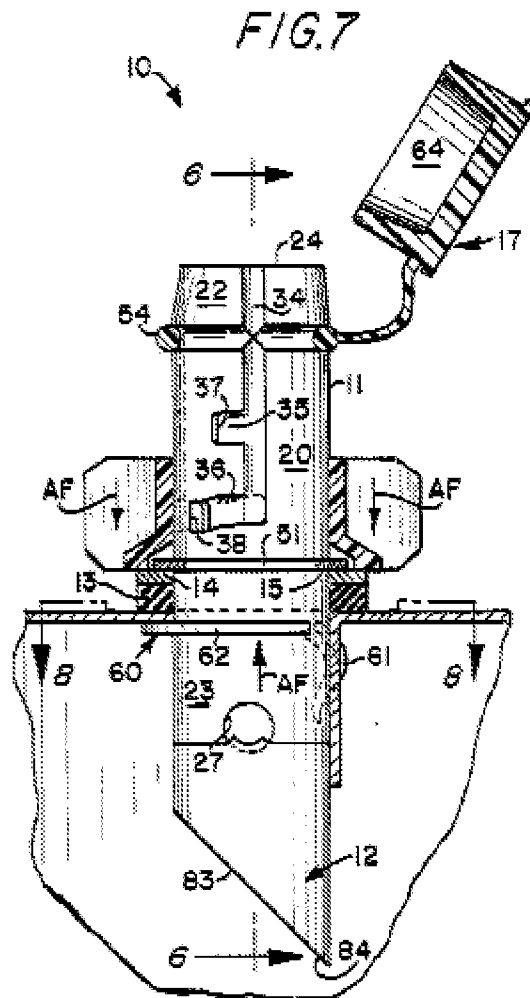
Tallman teaches a dispensing spout (10) that is designed to be pierced through a container (C), the spout including a rim (60) that engages the interior surface of the container (C)(see fig. 7, *infra*). This provides a secure fit to the container.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the attachment mechanism of Tallman in the connector device of Kawaguchi in order to provide a secure fit.

Furthermore, where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their

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established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.



Regarding claim 19, the Kawaguchi's connector (12) requires significant force to remove from the enteral administration set (30) is interpreted herein as being relatively non-releasable compared to a connector that lacks barbs (JR)(fig. 6).

The term "rigid" and "flexible" in claims 31, 32 and 34 are relative terms which renders the claim indefinite. The terms "rigid" and "flexible" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such, Tallman's first and second rims (13, 14, 60) can be fairly considered to be either rigid or flexible.

Regarding claim 33, Tallman's first rim means (13, 14) is a flange, see fig 7.

Regarding claim 36, Tallman's second rim (60) can be reasonably construed as a thickened portion of the connector (10).

6. Claims 30 and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi in view of Hegi (US 3,599,836).

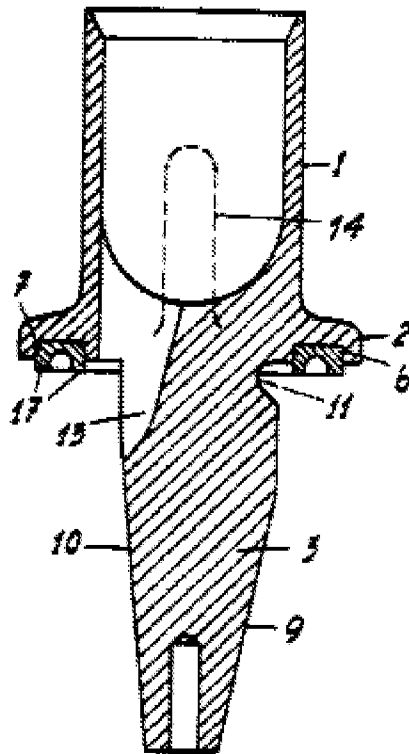
Kawaguchi does not teach an attachment means fixedly attaching the connector device (12) to an interior surface within the paper packaging system (20).

Hegi teaches a dispensing spout (1) that is designed to be pierced through a container, the spout including a rim (11) that engages the interior surface of the container (see fig. 2, *infra*). This provides a secure fit to the container.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the attachment mechanism of Hegi in the connector device of Kawaguchi in order to provide a secure fit.

Regarding claim 35, Hegi teaches that the rim (11) is a recess (see fig. 2, *infra*).

Fig. 2



Response to Arguments

7. Applicant's arguments with respect to claims 2, 3, 7, 8 and 10-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization

where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Bogart/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761